E. Clayton Teague
Director, National Nanotechnology Coordination Office

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Introduction

Mr. Chairman and members of the Committee, thank you for inviting me to testify at this hearing. I consider it a high honor. My name is Clayton Teague and I am the Director of the National Nanotechnology Coordination Office (or NNCO). The NNCO provides technical and administrative support to the Nanoscale Science, Engineering, and Technology (or NSET) Subcommittee of the National Science and Technology Council's Committee on Technology. The NSET Subcommittee is the interagency body that coordinates, plans, and manages the National Nanotechnology Initiative (or NNI). It is a privilege for me to speak on behalf of all of the 24 agencies that participate in the NNI and representatives on the NSET Subcommittee. For the past two and a half years, I've had the opportunity of working with staff members of these agencies; I assure you they are sincerely dedicated to the missions of their agencies – including protecting public health and the environment. Many of them unselfishly and intentionally have devoted their entire professional careers to these worthy purposes. My testimony today reflects and is a tribute to their efforts and initiative.

The message that I want to communicate to you today is that the agencies participating in the NNI are working together proactively and have put in place broad and strong coordination and planning activities to understand and address the environmental and safety implications of nanotechnology. Through the NNI, the Federal Government is funding forefront environmental, health, and safety (EHS) research to establish a strong foundation and much progress in understanding EHS implications has been made. In this effort, the NNI is engaged and coordinating with industry and other countries to promote the responsible development of nanotechnology. Finally, NNI-supported studies are providing useful preliminary information, but more research is needed.

Nanotechnology is the understanding, control, and use of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. It is a truly transformational technology, promising widespread applications in many fields, ranging from energy and medicine to agriculture and manufacturing. As these applications move from the laboratory to practical use, nanotechnology has the potential to help strengthen the economy, protect homeland and national security, improve public health and the environment, and raise the quality of life for all people.

With such powerful promise, the Administration is committed to fostering this emerging technology. The Administration is equally committed to achieving these benefits in a responsible manner – including consideration of benefits and possible negative environmental and safety implications. (In the updated NNI Strategic Plan released in 2004, one of the four overarching goals is to "support responsible development of

nanotechnology.") We are here today to discuss these implications, and the research that is needed to address them.

Since it was launched in 2000, the NNI has recognized the need to evaluate the environmental and safety implications of this promising technology. As the efforts to develop new nanoscale materials and devices have grown, so too have efforts aimed at improving our understanding of novel properties of nanomaterials, and risks that may arise from those properties. This increased understanding has in turn guided the agencies' research programs on environmental, health, and safety (or EHS) implications of nanotechnology.

These research programs should continue to be performed concurrently with other nanotechnology research. The United States' investment in nanotechnology research represents only one quarter on the investment by governments worldwide. The global pace of innovation is accelerating and other nations are not going to voluntarily slow down in their efforts to reap the potential of nanotechnology. The current approach whereby EHS research is informed by and performed concurrently with scientific, product and process research will ensure that environment and safety concerns are addressed, while maximizing progress toward realizing nanotechnology's economic and societal value to the Nation.

I want to make two points at the outset.

1. *Most nanotechnology-based products pose little chance for public exposure and therefore pose little risk to health or the environment.* Most uses of nanotechnology today are in composites where the nanoparticles are bound in a matrix (e.g., in golf clubs or car bumpers) or in nanoscale structures that are part of larger devices (e.g., in electronic circuits). Contact with these items generally poses no greater risk than with the versions not containing engineered nanomaterials. Concern is focused on possible risk due to exposure to the relatively small number of end-use products that contain "free" (i.e., unbound) engineered nanomaterials, which may be inhaled, ingested, or absorbed through the skin or that may find their way into the air, soil, or aqueous environment.

2. *Manufacturers already minimize exposure to fine particles in the workplace.* The greatest likelihood of exposure to engineered nanomaterials is during manufacture (of nanoparticles or using nanoparticles). It is widely known that inhalation of fine particles in conventional industrial operations should be avoided, and the Federal Government, particularly National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA), provides guidance that covers areas such as design and use of ventilation systems, personal protective equipment use, and laboratory practices to minimize such exposure in the workplace. Therefore, minimizing inhalation and dermal exposure to engineered nanomaterials is recommended and the principles guiding efforts to limit exposure should be very similar to those used to limit exposure to other fine particles.

The purpose of these points is not to downplay potential risks associated with nanotechnology, but to put these issues in context. Exposure to free engineered nanomaterials (as opposed to fine particles that are naturally occurring or that are the incidental byproducts of human activities such as combustion or welding) is for the most part still low. So we are well positioned to assess possible risks before nanoparticles become widely used or make their way into the environment in large quantities.

So what is the Federal Government doing to understand and address the possible risks of nanotechnology to people and the environment?

The agencies participating in the NNI are working together proactively and have put in place broad and strong coordination and planning activities to understand and address the environmental and safety implications of nanotechnology.

Within our interagency NSET Subcommittee, a number of subgroups have been established to address specific areas of interest or concern. One of these subgroups—established in 2003—is the Nanotechnology Environmental and Health Implications (NEHI) Working Group. NEHI brings together representatives from some 24 agencies that support nanotechnology research or that have regulatory responsibilities to exchange information and to identify, prioritize, and implement research needed to support regulatory decision-making processes. Through the efforts of the NEHI Working Group, regulatory agencies have been proactively engaged with each other and the research agencies, leading to earlier awareness of relevant issues and expedited activities to address them. In addition, those agencies that are primarily focused on research have a greater appreciation for the issues confronted by the regulatory bodies.

As an aside, many NEHI Working Group members have commented on how unusual it is for issues to be discussed among the regulatory agencies, much less with research agencies. In remarks before a National Academies panel, Norris Alderson, FDA Associate Commissioner for Science, noted that in his more than 30 years with the FDA, he does not recall the regulatory agencies sitting down together to discuss a subject that crosses regulatory boundaries and authorities before he did so in the NEHI Working Group.

Currently, the NEHI Working Group is developing a coordinated approach to nanotechnology research in the area of environmental, health, and safety (EHS). With input from industry and other non-governmental groups, the Working Group is preparing a document that identifies and prioritizes information and research needs in this area. The document will serve as a guide to the NNI agencies as they develop budgets and programs and will inform individual investigators as they consider their research directions. It will also provide a measure of confidence on the part of policymakers, such as you, and the public. We look forward to sharing this document with this Committee when it is complete.

The NSET Subcommittee has also formed a formal working group to liaise with various industrial sectors, including both the chemical and semiconductor industries. Through these activities, industry is providing input to the NNI regarding pre-competitive and

non-competitive research needs that those industries deem critical to the successful transition of nanotechnology. Both of these industrial sectors have identified EHS research as an important area for government and industry research, and their input will inform the NEHI Working Group efforts to plan and coordinate NNI programs on the subject.

Finally, the NSET Subcommittee supports a number of international activities related to the topic of nanotechnology and EHS. Concerns about possible environmental and safety implications of nanomaterials are not confined to the United States; research needs are universal. Sharing of information, coordination of research agendas, and collaboration on non-competitive issues benefits everyone. The NNI activities are coordinated through the informal Global Issues in Nanotechnology Working Group, formed in 2005 and led by the State Department.

Through the NNI, the Federal Government is funding forefront EHS research to establish a strong foundation and much progress in understanding EHS implications has been made.

As stated in the NNI Supplement to the President's FY 2006 Budget, the NNI will support nearly $39 million this year on research and development whose primary purpose is to understand and address potential risks to health and the environment posed by exposure to nanomaterials and nanoproducts. This estimate does not include considerable research that is taking place as part of efforts that help advance understanding of nano-EHS implications but that are not focused primarily in this area. For example, many projects funded by the National Institutes of Health to develop nanomaterials for therapeutic applications routinely include basic toxicity testing, although such testing is not the primary purpose of the research. Moreover, this estimate does not include substantial investment in research on the effects of incidental ultra-fine and nano-particles, such as diesel exhaust and power plant emissions.

The NNI research on environmental and health implications is being funded by several agencies, including EPA, NIOSH, NSF, NIH, NIST, USDA, DOD, and DOE. Where appropriate, agencies are working together in a carefully coordinated effort to address research areas that fall within more than one agency's mission or that require multiple agencies' expertise.

Examples of multi-agency activities include:

- ❒ EPA, NSF, NIOSH, and NIEHS plan to issue a joint solicitation to support approximately $8 million of research on environmental and human health implications of nanotechnology in 2006. EPA will manage peer review of the proposals, and all four agencies will select from among those that pass review for funding based on agency relevancy and interest. A similar collaboration among EPA, NSF, and NIOSH in 2005 led to about $7 million in funding for research on the same topic.

- ❒ The Nanotechnology Characterization Laboratory (NCL) is supported by a partnership among the National Cancer Institute, NIST, and the FDA. The NCL, which was established in 2005, provides critical expertise and infrastructure for

developing and performing safety tests in order to expedite the use of nanomaterials for the diagnosis and treatment of cancer. The expertise of all three agencies is vital to the successful operation of the Laboratory.

- ❒ The National Toxicology Program (NTP) is an ongoing partnership among NIH's National Institute of Environmental Health Science (NIEHS), FDA's Center for Toxicological Research, and CDC's NIOSH. Beginning in 2004, the NTP initiated a series of toxicity studies on classes of nanomaterials that are especially promising in a range of applications—carbon "buckyballs" and carbon nanotubes, nanoscale powders of metal oxides, and semiconductor "quantum dots." The early results of these studies are expected in the coming year.

I also want to highlight the research program established in the past two years by NIOSH. As discussed above, while free engineered nanoparticles are not found in most nanotechnology-based products, workplace exposure during manufacture may be cause for some concern. Accordingly, NIOSH has launched an aggressive research program to assess potential toxicity of nanomaterials found in the workplace, and has produced a preliminary document recommending best practices for safe handling of nanomaterials in the workplace. Information on these and other NIOSH activities with respect to nanotechnology are posted on the NIOSH website (http://www.cdc.gov/niosh/topics/nanotech/).

In addition to the various activities within and among the participating Federal agencies, the NNI participates in a number of bodies on the international level. Such activities will help to promote responsible development of nanotechnology worldwide.

Organization for Economic Cooperation and Development (OECD): Within the OECD Environmental Directorate, the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology hold regular joint meetings. The next such meeting will be hosted by the United States in the Washington area on December 7-9 and will take the form of a workshop on the safety of manufactured nanomaterials. The objectives of the workshop are to determine the state of the art regarding safety assessment of manufactured nanomaterials and to identify future needs for risk assessment within a regulatory context. The resulting report is expected to discuss issues including nomenclature, human health, environmental hazards, exposure assessment, and possible regulatory frameworks.

International Life Sciences Institute (ILSI): Representatives from EPA and NIOSH participated in a working group convened by the ILSI Research Foundation Risk Sciences Institute to develop a screening strategy for identifying hazards of engineered nanomaterials. The group recently reported on the elements of such a strategy, and recommended broad data gathering. The report acknowledges that at this early stage, there are insufficient data to support a specific testing protocol.

The International Dialogue on Responsible Research and Development of Nanotechnology: The first Dialogue, sponsored by NSF, was held in June 2004 in Alexandria, Virginia, and brought together 25 countries and the European Commission (EC) to discuss environmental, health and safety issues as well as ethical, legal and

other social issues. A follow-up meeting was hosted by the EC in Brussels last July, and a next meeting is planned in Summer of 2006 to be hosted by Japan.

International Standardization Organization (ISO) and American National Standards Institute (ANSI) : A critical aspect of protecting health and the environment and a basis of any regulation of chemicals and materials are standardized tools and methods for measuring and monitoring exposure. Research related to measurement science and technology is led by NIST. However, standards are developed jointly by all stakeholders through consensus-based processes. In June 2004, in response to a letter from Dr. John Marburger, Director of the Office of Science and Technology Policy, the American National Standards Institute (ANSI) established a Nanotechnology Standards Panel to facilitate and coordinate nanotechnology standards development in the United States. The NSET Subcommittee and the relevant agencies are members of the Panel and its Steering Committee, and are providing financial support to facilitate its activities.

Subsequently, the International Organization for Standardization (ISO) has established a Nanotechnologies Technical Committee, which held its first meeting last week. As Chair of the ANSI-accredited Technical Advisory Group (TAG) to the ISO and leader of the U.S. delegation, I am pleased to report that the United States will lead the Working Group on Health, Safety, and Environmental Aspects of Nanotechnologies. Our first action will be to submit the NIOSH document on “Approaches to Safe Nanotechnology” to the ANSI TAG as a possible work item for the ISO Working Group. If approved the document will be put forth to the ISO Working Group as a draft to be further developed with inputs from other ISO Technical Committee member countries. Once developed and approved by the Technical Committee, the document will be issued as an international Publicly Available Specification; an informational document available to all countries.

The ISO Technical Committee’s granting of leadership in the area of environmental and safety aspects of nanotechnology to the United States is an acknowledgement that we are at the forefront in this area.

NNI-supported studies are providing useful preliminary information, but more research is needed.

Preliminary research to date shows, not surprisingly, that not all nanomaterials are alike. Earlier this month, researchers at Rice University released results showing that the toxicity of carbon nanotubes can be reduced by engineering of the nanotube surface, as they had shown earlier for buckyballs. Such data indicate that, unlike naturally occurring or incidental nanoparticles, engineered nanomaterials may be tailored to reduce toxicity.

In another study published recently in the journal *Pharmaceutical Research*, a group headed by Dr. Russell Mumper at the University of Kentucky, tested nanoparticles coated with polyethylene glycol (PEG), a polymer used to protect many types of therapeutic agents from elimination by the immune system. The investigators developed a test to determine how PEG-coated nanoparticles affected a variety of *in vitro* and *in vivo* parameters, including blood clotting time, red blood cell damage, and platelet

aggregation or clumping. They found that a concentration of nanoparticles one might expect in the blood stream produced no untoward biological effects on blood cells.

These two studies are only a sampling of the wide range of work underway within the NNI. While time does not permit me to describe the work taking place across all of the agencies that support research on environmental and safety implications of nanotechnology, I encourage you to see the NNI FY2006 Supplement to the President's Budget and the NNI website, www.nano.gov, for additional detail.

Current research is providing data that are helping us understand the way nanomaterials interact with biological systems and the environment. However, substantial work remains, including in the following areas.

- ❒ Methods and metrics for determining nanoparticle exposure and dose received among workers, consumers, and the environment, as well as fate and transport once the dose is received.

- ❒ Methods for controlling exposure in the workplace, including monitoring and personal protective equipment.

- ❒ Analytical methods for characterizing nanomaterials properties and behavior. Most toxicologists and the general research community agree that new toxicity tests/methods are not needed for nanomaterials. What is needed is the application of novel (to toxicologists) physical/chemical characterization and detection methods so that researchers can be assured the materials being studied have the expected and desired properties. The unfortunate fact that so many toxicology papers on nanomaterials are difficult to interpret is not because the toxicology study protocols are not up to the task, it's because the reporting of the characterization of the materials is inadequate.

- ❒ Experimental and computational approaches to determine biological effects, including toxicity

- ❒ Methods for assessing and managing risk of nanomaterials.

The research needed in this area will be addressed by the various stakeholders, including not only the Federal Government, but also industry and research institutions. The Federal Government will play an important role through its broad support of research, including basic research on the environmental and health effects of nanomaterials. The Government supports research aimed at understanding nanomaterials and how they interact with cells, organisms, and the environment. The Government also supports research aimed at developing tools and methods for measuring and assessing nanomaterials. Such research expands knowledge and understanding, and supports the Federal Government's regulatory role by enabling science-based decision-making.

Yet, we know that much more needs to be done, and many questions remain unanswered. We should not expect that we will have all of the answers quickly. Research takes time, especially on a subject this complex. We already know that all

nanomaterials are not created equal in terms of potential hazard or potential exposure. A carefully designed research plan, along with shared Government and industry responsibility and collaboration should guide our efforts. We must evaluate research results carefully, and if we discover that there are dangers associated with certain materials in specific uses, we should determine what restrictions might be necessary, including applying current regulatory authorities. Above all we need to be guided by science, not by irrationality or emotion. Finally, we need to communicate effectively and openly with the public. Nothing else will establish trust and credibility.

Thank you for the opportunity to speak today on this important aspect of nanotechnology.